UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/444,711	11/24/99	YEATMAN	T 114205.400

EXAMINER	
HARRIS, A	
ART UNIT	PAPER NUMBER
1642	9

021269
PEPPER HAMILTON
600 FOURTEENTH STREET NW
WASHINGTON DC 20005

HM12/0207

DATE MAILED: 02/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/444,711	Yeatman And Irby
Examiner	**Group Art Unit**
Alana M. Harris, Ph. D.	1642

☒ Responsive to communication(s) filed on *November 27, 2000.*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-28* is/are pending in the applicat

Of the above, claim(s) *2, 5-8, 12-18, 20, and 28* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 3, 4, 9-11, 19, and 21-27* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2 and 3.* filed 3/15/00 & 3/21/00, respectively

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I (claims 1, 3, 4, 9-11, 19 and 21-27) in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-28 are pending.

Claims 2, 5-8, 12-18, 20 and 28, drawn to non-elected inventions are withdrawn from examination.

Claims 1, 3, 4, 9-11, 19 and 21-27 are examined on the merits.

Information Disclosure Statement

3. The information disclosure statements filed March 15, 2000 and March 21, 2000 as Paper Numbers 2 and 3, respectively appear to be duplicates of one another. The Examiner has reviewed all the documents listed.

Drawings

4. The drawings are objected to because of reasons cited on attached form PTO 948 completed by draftsman. Correction is required.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 25 is broadly drawn to "An isolated nucleic acid consisting essentially of a nucleotide sequence of SEQ. ID. NO:1". The specification while being enabling for the nucleic acid having the sequences of SEQ. ID. NO:1, does not reasonably provide enablement for variants that have at least 90% sequence identity. There is no guidance as to how to make these divergent sequences, which are to encode a non-receptor tyrosine kinase function. It would seem that specific function(s) would be required to make a protein encoded by these variants useful for the applications disclosed in the specification. The specification does not teach what those are or

how to determine what they are. This could possibly be a vast collection of polynucleotides and the specification provides inadequate instruction to allow one skilled in the art to make and use the said variants having at least 90% sequence identity with a reasonable expectation of success and without undue experimentation.

7. Claims 1, 3, 4, 9-11, 19 and 21-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 4, 9-11, 19 and 21-27 are broadly drawn to isolated nucleic acids and genes consisting essentially of SEQ ID NO:1 encoding a c-Src mutant protein and an expression construct for expressing all or a portion of c-Src SRC 531 mutant contained in a host cell. Additionally, claims are broadly drawn to isolated nucleic acid consisting essentially of a nucleotide sequence that is at least 90% identical to SEQ ID NO:1. Thus, all cited claims are broadly drawn to a genus of nucleic acid molecules that contains portions of nucleic acids that encode the mutant protein,. The specification describes only the cDNA sequences of SEQ ID NO:1, which translates to the 536 amino acids. The specification does not describe any of the structural elements of a gene that would encode these actual DNA sequences of promoter and regulatory regions and introns, all defining elements of a "gene". The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the

broadly claimed invention at the time the instant application was filed. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Likewise, the specification does not contain any disclosure of the function of a full length open reading frame (ORF) that includes SEQ ID NO:1. The genus of cDNAs including SEQ ID NO:1 is very large and members of the genus are variable because of the potentiality of the many different proteins they may encode. Therefore, many structurally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. One skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 3, 4, 9, 11 and 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 24 and 25 are vague and indefinite for reciting "...consisting essentially of a nucleotide sequence...". The term "consisting essentially of" is indefinite because the metes and bounds of the claimed invention cannot be determined. In the absence of a definition in the specification, it cannot be determined if "consisting essentially of" is reading on narrow or open language. For examination purposes, it will be given the broadest reasonable interpretation in view of open language.

b. The recitation "truncated" in claim 3 is vague and indefinite. How much of the oncogene is truncated? What domains are missing or included? It is impossible to determine the metes and the bounds of the claimed invention.

c. The recitation "SRC 531" in claims 9 and 11 are vague and indefinite. The applicant is advised to amend the claims to include the full terminology. The recitation "SRC 531" is indefinite in that it only describes a gene encoding a protein of interest by an arbitrary name. While the name itself may have some notion of the activity of the protein, there is nothing in the claims which distinctly claims the protein. Others in the field may isolate the same SRC 531 protein and give such an entirely different name. Applicant should particularly point out and expound on the characteristics associated with the protein. Claiming molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what the protein is.

d. The recitation "fragment thereof" in claim 24 is vague and indefinite. It is not clear what is encompassed by the fragment. Does the term constitute a certain number of nucleic acid

residues? Accordingly, as written, it is impossible for one skilled in the art to determine the metes and bounds of the claimed invention.

e. The recitation "tyrosine kinase-like activity" in claim 24 is vague and indefinite. It unclear what actual functions would be considered "tyrosine kinase-like".

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 3, 4, 9-11, 19 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cartwright et al. (Cell 49:83-91, April 10, 1987/Referenced on IDS). Cartwright discloses in the Summary section of page 83 a gene comprising a truncated c-Src oncogene wherein the truncation occurs at the 3' end or C-terminal end of pp60 c-Src. The truncated pp60 c-Src protein is lacking 17 carboxy-terminal amino acids. This isolated DNA molecule encodes a Src protein tyrosine kinase lacking the carboxy-terminal end.

The Examiner is interpreting the mutant protein of Cartwright to read on Applicants' mutant protein designated as SRC 531. An oligonucleotide segment encoding the mutated c-src genes was subcloned into an retrovirus expression vector, p*neo*MLV to create several plasmids (see Results section, page 83). NIH 3T3 cells were transfected with the plasmids which contained a promoter and an oligonucleotide segment located downstream of the promoter and wherein transcription of the segment is initiated at the promoter. The disclosed contiguous fragment encoded a polypeptide that exhibited tyrosine kinase activity or tyrosine kinase-like activity (see page 86, column 1, first full paragraph).

12. Claims 1, 9-11, 19 and 21-27 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,336,615 (August 9, 1994). U.S. Patent #5,336,615 discloses a recombinant nucleic acid or its complement that is at least 90% identical to the nucleotide sequence of SEQ ID No:1 (see columns 21-28 and accompanying database sheet). The c-src gene or a part was located downstream of a promoter and wherein transcription of the gene or part was initiated at the promoter contained within an expression construct (see column 7, lines 51-55, and column 9, lines 1-5 and lines 22-25). Bovine calf aortic endothelial host cells were infected with a retroviral vector containing the c-src gene or part consisting essentially of a nucleotide sequence of SEQ ID NO:1 or a contiguous fragment wherein said isolated nucleic acid encoded a polypeptide exhibiting tyrosine kinase activity or tyrosine kinase-like activity (see

column 13, line 66-column 14, line 2). Also disclosed is a method for producing and purifying the kinase protein (see column 11, lines 1-60).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 3:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)306-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
February 2, 2001

SHEELA HUFF
PRIMARY EXAMINER